ABET Addendum

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Needs

- **Low Input Impedance:** To design a headset combines the qualities found in a wet – high signal quality from its low input impedance – with the comfort and ease of use of a dry EEG system.
- **Low-Cost Manufacturing:** Considering the high cost of many existing EEG headsets (upwards of $10K USD), there is a need to design a product using 3D-printed parts which brings down manufacturing costs by a large sum.

Constraints

- **Safety:** Because the headset is a medical device which requires direct skin contact, there are risks of irritation, electrocutions, electrode contamination, and puncture wounding.
- **Manufacturability:** Manufacturing the hydrogel electrode requires preparation of the ingredients (with expensive base material), molding, and curing which takes up much time.
- **Quality Control/Marketability:** Because manufacturing of hydrogel electrodes took up much time, quality control of the hydrogel electrodes was effectively reduced.

Engineering Standards

- **ISO 10993-1** — This standard governs biological evaluation of medical devices which is applicable given direct scalp contact by hydrogel electrodes and electrode tips.
- **ASTM F1904-23 —** The standard is relevant for the potential of the deposition the hydrogel may cause on the scalp and ensures we have a safely operable device.
- **ISO 14155 —** Ensures that the device meets any regulation for potential clinical use.

Concerns

- **Societal:** Hydrogel formulation must be non-irritating and free of cytotoxic compounds at scalp contact.There is a risk of electrocution during use of the hydrogel and electrodes.
- **Ethical:** Any software implementation requires informed consent protocols and secure, compliant data storage.
- **Environmental:** Because the headset is mostly manufactured through 3D printed plastics, there is a concern of plastic waste from many design iterations during the project.

Teamwork

- The project was split into two subteams — hydrogel electrodes and adjustable headstrap — with task ownership clearly delegated by the project lead.
- Active communication and cross-team openness during work sessions ensured effective subproject integration and constructive iteration.

Motivation

- Existing EEG headsets systems fail to meet the high-signal quality, cost, or accessibility requirements of many target user populations.
- The project's multidisciplinary scope enabled each member to contribute within their area of expertise while developing cross-functional understanding across subteams.

Innovation

- The primary innovation of the team is a semi-dry hydrogel electrode with a comb-like structure, which achieves the signal quality of wet electrodes and the ease of use of dry electrodes while avoiding the limitations of both.